

**STATE HEALTH PLANNING BOARD
CERTIFICATE OF NEED PROJECT SUMMARY
LUNG TRANSPLANTATION SERVICES**

Applicant:	Newark Beth Israel Medical Center (NBI)
CN Number:	FR 060607-07-01
Location:	Newark, Essex County
Project Cost:	\$0

PROJECT DESCRIPTION

Applicant is proposing to provide lung transplantation services to all New Jersey residents. As clarified in completeness responses, the applicant is seeking certification for an adult lung transplant program, serving the age 17 and older age group population. There are no construction or project costs associated with this project.

A. APPLICANT JUSTIFICATION

NBI states that it demonstrates institutional commitment, capability, preparedness and capacity to provide a successful lung transplant program capable of serving all New Jersey residents that can be quickly implemented. A lung transplant program located in New Jersey will provide significant positive impacts for New Jersey residents' access to lung transplant services, particularly, the under-or uninsured. Geographical access will also be greatly enhanced for most New Jersey residents. In addition, having a state program will promote increased organ donation and increase available organs for lung transplant candidates. Furthermore, having an in-state program will decrease the number of discarded donor lungs, which have a very short usable life.

NBI states that it is well positioned to provide a lung transplant program, citing its previous experience with lung transplants, which makes it uniquely qualified, as well as NBI's experience with its heart transplant program. NBI states that it was the 7th leading volume adult program in the country in 2005. NBI also states that its heart transplantation outcomes are comparable or exceed the nation's most respected transplant centers. NBI also states that its history of providing heart transplant services reflects that this service is open to all regardless of a patient's racial, ethnic or socioeconomic status.

B. STATUTORY CRITERIA

- a. The availability of facilities or services that may serve as alternatives or substitutes.

The applicant states that there are no lung transplant programs in New Jersey. New Jersey residents in need of lung transplantation must be referred out of state, with most patients being wait listed at Temple University or University of Pennsylvania Hospital in Philadelphia or New York Presbyterian Hospital.

TABLE 1.
New Jersey Residents on Waiting Lists for Heart/Lung and Lung Transplant

			List Year		
			2003	2004	2005
Center	Organ	Age	0	1	0
St. Luke's-Florida	Heart-Lung	18+			
Loyola UMC- Illinois	Lung	18+	1	0	0
Ochsner-Lousinana	Lung	18+	0	1	0
Barnes-Jewish Hospital-Missouri	Heart-Lung	18+	0	1	0
Duke-North Carolina	Lung	18+	1	3	1
University of North Carolina	Lung	18+	0	1	1
Presbyterian NY	Heart-Lung	0-17	1	0	0
		18+	0	0	1
	Lung	0-17	1	1	1
		18+	10	14	17
Mount Sinai NY	Lung	18+	0	1	3
Children's Hosp Philadelphia	Lung	0-17	0	1	0
University of Pittsburgh	Heart-Lung	18+	0	1	0
	Lung	18+	0	1	0
Temple University	Heart-Lung	18+	0	1	0
	Lung	18+	4	9	13
University of Pennsylvania	Heart-Lung	18+	0	1	0
	Lung	0-17	1	0	0
		18+	37	29	10
Inova Fairfax-Virginia	Lung	18+	1	0	0
Children's Hosp. Wisconsin	Lung	0-17	1	0	0
	Heart-Lung	0-17	1	0	0
		18+	0	5	1
	Lung	0-17	3	2	1
		18+	54	59	45
Total			58	66	47

Source: UNOS, OPTN Data Registry as of May 19, 2006

TABLE 2.

New Jersey Residents on Waiting List for Lung Transplantation Age greater than 17

Transplant Center	2003	2004	2005
Loyola UMC- Illinois	1	0	0
Ochsner- Louisiana	0	1	0
Duke-North Carolina	1	3	1
University of North Carolina	0	1	1
Presbyterian NY	10	14	17
Mount Sinai NY	0	1	3
University of Pittsburgh	0	1	0
Temple University	4	9	13
University of Pennsylvania	37	29	10
Inova Fairfax-Virginia	1	0	0
Totals	54	59	45

Source: UNOS, OPTN Data Registry as of May 19, 2006

TABLE 3.

UNOS Region Where New Jersey Residents Received Lung Transplantation in 2005

Region	Organ		Total
	Heart-Lung	Lung	
2 (DE, MD, NJ, PA, WV & Wash D.C.)	1	31	32
9 (NY & VT)	0	11	11
11 (KY, NC, SC, TN, & VA)	0	1	1
Total	1	43	44

Source: UNOS, OPTN Data Registry as of May 19, 2006

The applicant is seeking certification for an adult lung transplant program, serving the age 17 and older age group population. The applicant states that pediatric patients are transferred to out of state facilities through physician referral. As noted in Table 1, there was one New Jersey pediatric patient wait listed at an out of state lung transplant program, two in 2004 and three in 2003.

- b. The need for special equipment and services in the area.

The applicant states that there is a need for a permanently licensed lung transplant service in the area and statewide. A lung transplant program at NBI will provide an in-state service and increase organ donation. The applicant states that during 2000 to 2005, 123 New Jersey lung transplant registrants died while awaiting a transplant and seven became ineligible because their medical condition deteriorated.

The Department approved NBI to perform lung transplants on a case by case basis from 1992 until 1997, at which time NBI discontinued this arrangement.

- c. The adequacy of financial resources and sources of present and future revenues.

The applicant states it has the financial resources to implement this project.

The Department notes that the applicant has documented adequacy of its financial resources and sources of present and future revenues to satisfy the statutory and regulatory requirement that the project can be economically accomplished and maintained.

- d. The availability of sufficient staff in the several professional disciplines involved.

The applicant states it has staff that can currently support lung transplantation services. For those additional staffing needs, the applicant states it will utilize the Saint Barnabas Health Care System's recruitment methods. In addition, the applicant states that the ability to recruit will be enhanced upon establishment of a permanent program.

The Department notes that the applicant has most of the required staff in place and will need to recruit for the transplant surgeon and transplant physician positions.

- e. The project is necessary to provide required health care in the region.

The applicant states that there are no other lung transplant programs in New Jersey.

- f. The project will not have an adverse impact on access to health care services in the region or Statewide.

The applicant states that there are no other lung transplant programs in New Jersey which would be impacted.

The Department notes that although there are no lung transplant programs in New Jersey, three out of state transplant programs would be impacted by a new program in New Jersey. UNOS data reports the following lung transplant activity:

In 2005, Temple University performed 15 lung transplants, with four being New Jersey residents. Temple had 36 patients wait listed in 2005, with 13 being New Jersey residents.

In 2005, Hospital of the University of Pennsylvania (HUP) performed 59 lung transplants, with 26 being New Jersey residents. HUP had 32 patients wait listed in 2005, with 10 being New Jersey residents.

In 2005, New York Presbyterian Hospital performed 43 lung transplants, with nine being New Jersey residents. Presbyterian had 80 patients wait listed in 2005, with 17 being New Jersey residents.

C. DEPARTMENT STAFF REVIEW

I. ACCESS/SERVICE AREA

NBI is located in Newark in Essex County. According to the US Census Bureau figures for 2002, 54% of the Essex County population is non-white. Within the city of Newark, 72.2% of the population is non-white. In addition, 15.6% of the Essex County population is living below the poverty level.

The applicant claims to be the third largest provider of charity care in the state. The Department confirms that NBI received \$37,093,643 in the SFY07 Charity Care Subsidy, which is the third largest subsidy in the state.

NBI's states that its heart transplant program services those in need regardless of the patient's ability to pay. NBI performed 39 heart transplants in 2005, two of those being Charity Care/Self pay and two being Medicaid recipients. *NBI states that it will provide similar access to uninsured lung transplant candidates.*

Table 4.
Heart Transplant Volume by Payer at New Jersey Programs in 2005

	CHARITY/ SELF PAY	COMM.	HMO	MEDICARE	MEDICAID	NJ BC	TOTALS
NBI	2	5	9	13	2	8	39
RWJUH	1	0	0	4	1	2	8

Source: NJ UB data

Given that a lung transplant would serve a statewide population, geographic accessibility is also a consideration. *NBI is located near major roadways, including the New Jersey Turnpike, the Garden State Parkway, and Routes 1, 9, 78 and 22. The applicant states that it is accessible by public and private transportation, including buses, trains and the Newark Airport.*

The certificate of need and licensure rules for transplantation services, N.J.A.C.8:33Q, do not differentiate pediatric from adult transplantation; therefore, the applicant would have the ability to perform pediatric procedures. *The applicant states in its completeness responses that it would seek certification as an adult (age >17) lung transplant program.*

The Department notes that of the 411 heart transplant performed at NBI to date, two were pediatric cases (one in 2004 and one in 1993). With respect to kidney transplantation, the applicant performed 13 pediatric kidney transplants, but none have been performed since 1997. None of the lung transplants previously performed by NBI were pediatric cases.

The CN approval and subsequent licensure for lung transplantation would enable NBI to become eligible to seek certification to perform heart/lung transplantation. *NBI states in its completeness responses that it will seek UNOS certification for lung transplantation only.* As displayed in Table 1, the need for heart/lung transplantation is relatively small, with one New Jersey resident wait listed in 2005 and five in 2004.

Becoming a lung transplant program would also qualify NBI to perform Lung Volume Reduction Surgery (LVRS). This procedure helps people with severe emphysema by removing about 30% of the most diseased lung tissues so that the remaining healthier portion can perform better. As a result of a large clinical trial, the Centers for Medicare and Medicaid Services recently approved coverage for certain LVRS procedures at hospitals that are Medicare approved for lung transplants or credentialed by the Joint Commission of Accreditation of Healthcare Organizations (JCAHO) under their Disease Specific Certification Program for LVRS. There are no programs currently approved in New Jersey to perform LVRS. Two New Jersey residents underwent LVRS in New York and four in Pennsylvania in 2005.

As an existing transplant center, NBI is a UNOS member in good standing which participates in organ allocation as prescribed by UNOS policies. The applicant states that it will abide by UNOS policies regarding lung transplantation and lung allocation.

The applicant states that having a state program will promote increased organ donation and increase available organs for lung transplant candidates. Furthermore, having an in-state program will decrease the number of discarded donor lungs, which have a very short usable life. The Department agrees with these statements. Organ allocation policies set out by UNOS distribute organs locally first, and if no match is found they are then offered regionally, and then nationally, until a recipient is found. Patients wait

listed at a New Jersey transplant center would be considered first, within the context of their medical status, when a New Jersey donor would become available. Also, there is

an initiative underway at the federal level to increase the number of organs harvested and transplanted per donor. A New Jersey lung transplant program will improve the two local organ procurement organizations' ability to meet these federal goals. NBI has been an active participant in other initiatives to improve organ donation and has expressed its support in reaching these goals.

II. UTILIZATION/VOLUME

The applicant is a licensed provider of heart and kidney transplantation which exceeded the minimum volume requirements for the last two years.

Table 5.
Heart & Kidney Transplant Volume at NBI

	Vol. Standard	As of 6/30/06	2005	2004
Heart	12	15	39	42
Kidney	25	16	53	52

Source: UNOS

NBI also performed a total of 31 lung transplants on a case by case basis upon approval by the Department up until 1997.

Table 6.
Lung Transplant Volume at NBI

	Total	1997	1996	1995
Lung	31	3	6	7

Source: UNOS

The applicant provided projections of lung transplant performance of two cases in year one, eight in year two and sixteen in year three. The Department questions the applicant's inclusion of Medicare patients in years one and two prior to the applicant's ability to apply for Medicare certification. Medicare requires ten cases to be performed in order for a program to apply for Medicare certification. In its completeness responses, the applicant stated that Medicare patients could pay out of pocket, or rely on a secondary insurer or grant funding.

There are no other lung transplant programs in New Jersey; however, there are three active adult lung transplant programs in Pennsylvania (Hospital of the University of Pennsylvania, Temple University Hospital and the University of Pittsburgh Hospital) and two in New York (Mount Sinai and New York Presbyterian.) All of these hospitals would be impacted to some extent since New Jersey residents are currently referred to those centers.

Table 7.
Lung Transplant Volume at Pennsylvania & New York Programs

	As of 6/30/06	2005	2004
Univ. of Penna.	31	59 (10)*	39 (29)*
Temple Univ.	23	36 (13)*	31 (9)*
Univ. of Pittsburgh	46	87 (0)*	58 (1)*
NY Presb.	27	43 (17)*	35 (14)*
Mt. Sinai	4	9 (1)*	4 (3)*

Source: UNOS

*The number of New Jersey residents wait listed at each center.

New Jersey residents are currently receiving access to lung transplantation at out of state programs; however, New Jersey's uninsured patients may not be able to access these programs. In 2005, there were 41 New Jersey residents who received a lung transplant in Pennsylvania and New York, of which there were no charity care/self pay cases. In addition, five of the 41 New Jersey lung transplant recipients in 2005 were non-white (12%).

Table 8.
NJ Residents Receiving Lung Transplants in Pennsylvania & New York By Payer in 2005

	CHARITY/ SELF PAY	COMM	HMO	MEDICARE	MEDICAID	NJ BC	TOTALS
Univ. of Penna.	0	0	13	8	5	0	26
Temple Univ.	0	0	3	1	0	0	4
NY Presb.	0	4	1	2	0	2	9
Mt. Sinai	0	0	0	2	0	0	2
Totals	0	4	17	13	5	2	41

Source: Penna. & NY UB data

The applicant states that the addition of a New Jersey lung transplant program will promote increased organ donation and increase available organs for lung transplant candidates. Furthermore, having an in-state program will decrease the number of discarded donor lungs, which have a short usable life. The Department agrees with this statement.

Table 9.
Donor Lung Recoveries

	As of 6/30/06	2005	2004
New Jersey	12	21	17
Pennsylvania	45	87	71
New York	23	43	21

Source: UNOS

III. STAFFING

The applicant states it has identified candidates for the transplant surgeon position who would meet the regulatory requirements. The applicant will also recruit a transplant pulmonologist for the program to serve as the required transplant physician. The applicant will utilize one of the existing four heart transplant coordinators as the lung transplant coordinator. The applicant states that all other staff required to implement the program are in place.

IV. INSTITUTIONAL COMMITMENT

The applicant is an existing heart and kidney transplant center that already has all of the required services, including laboratory facilities, in place. The applicant is proposing to perform only adult transplants; therefore, the pediatric requirements in the regulations are not applicable.

V. FINANCIAL

The Department performed a financial analysis which found the applicant has documented adequacy of its financial resources and sources of present and future revenues to satisfy the statutory and regulatory requirement that the project can be economically accomplished and maintained. There are no construction or project costs associated with this project.

D. STAFF RECOMMENDATION

The Department staff finds that the applicant, Newark Beth Israel Medical Center, has complied with planning rule requirements as set forth in N.J.A.C. 8:33 and 8:33Q in terms of access, utilization, staffing and institutional commitment. The applicant has also complied with the general criteria set forth in the Health Care Facilities Planning Act (N.J.S.A. 26:2H-8), as amended. In this specific case, NBI is currently licensed for heart and kidney transplantation seeking to perform lung transplantation. The Department staff have also found that the project is financially feasible.

Given the above, the Department staff recommends approval of Newark Beth Israel Medical Center's proposal to implement a lung transplant program with the following conditions. Given that NBI states that it will be focusing on adult lung transplantation, NBI is required to notify the Department sixty days prior to initiation of a pediatric lung transplant program. NBI would need to document its ability to provide appropriate staffing and a physical plant environment necessary for a pediatric lung transplantation program. NBI is also required to notify the Department sixty days prior to initiation of a heart/lung transplant program.